



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2015-0197; FRL-9942-99]**

**Fluazinam; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of fluazinam in or on cabbage, mayhaw, the cucurbit vegetable crop group 9, and the tuberous and corm vegetable subgroup 1C and amends the existing tolerance for “vegetable, *Brassica* leafy, group 5” to read “vegetable, *Brassica* leafy, group 5, except cabbage.” Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0197, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703)

305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfrNotices@epa.gov](mailto:RDfrNotices@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

*[http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0197 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0197, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## II. Summary of Petitioned-For Tolerance

In the **Federal Register** of May 20, 2015 (80 FR 28925) (FRL-9927-39), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5E8349) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fluazinam (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates in or on mayhaw at 2.0 parts per million (ppm); cabbage at 3.0 ppm; the squash/cucumber subgroup 9B at 0.05 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. The petition also requested to amend the tolerances in 40 CFR 180.574 in or on the vegetable, *Brassica* leafy, group 5 at 0.01 by changing it to read “vegetable, *Brassica* leafy, group 5, except cabbage” at 0.01 ppm and by removing the existing tolerance on potato at 0.02 ppm upon approval of the requested tolerance on the tuberous and corm subgroup 1C. That document referenced a summary of the petition prepared by ISK Biosciences, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

EPA is combining the existing tolerance for the melon subgroup 9A tolerance with the proposed squash/cucumber subgroup 9B tolerance and establishing a tolerance for the entire cucurbit vegetable crop group 9, rather than just subgroup 9B. The reason for these changes is explained in Unit IV.C.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for fluazinam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazinam follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

The liver is a primary target organ for fluazinam and numerous liver effects were observed in rats, mice, and dogs after oral and dermal exposure. After inhalation exposure,

portal of entry effects (increased lung/bronchial weights, alveolar macrophages and peribronchiolar proliferation) were seen.

Clinical signs were observed in an acute oral neurotoxicity study in rats; decreases in motor activity and soft stools were seen on the day of dosing at the limit dose. These effects were attributed to systemic toxicity and were not considered to be evidence of frank neurotoxicity. In two subchronic neurotoxicity studies (evaluated together) in rats, no evidence of neurotoxicity was observed. A neurotoxic lesion was observed initially in long-term studies in mice and dogs; however, the lesion is reversible and was later attributed to the presence of an impurity (Impurity-5) in the technical material. A NOAEL for the impurity was determined (based on the maximum concentration of Impurity-5 in technical grade fluazinam), equivalent to a NOAEL for central nervous system (CNS) effects of 20 mg/kg/day for technical grade fluazinam. The current acute and chronic reference doses selected for risk assessment are lower than the determined NOAEL and thus, protective of any possible neurotoxic effects resulting from exposure to Impurity-5.

In an immunotoxicity study in mice, significant suppressions of anti-SRBC AFC assay response were demonstrated at the highest dose tested indicating potential immunotoxicity. However, clear NOAELs and LOAELs were identified for the effects seen in the study and the points of departure (PODs) and endpoints selected for risk assessment are protective of immunotoxic effects.

There was no evidence of increased quantitative or qualitative susceptibility in the rabbit developmental or rat reproduction studies. However, quantitative susceptibility was seen in rat developmental and developmental neurotoxicity (DNT) studies where fetal/offspring effects were observed in the absence of maternal toxicity. The concern is low for the increased susceptibility noted in the studies since clear NOAELs are established, and the most sensitive

endpoints/PODs are used for risk assessment and are protective of the observed susceptibility. Therefore, the Food Quality Protection Act (FQPA) safety factor (SF) has been reduced to 1x.

Fluazinam is classified as having “Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential,” based on increases in thyroid gland follicular cell tumors in male rats and increases in hepatocellular tumors in male mice. Although there is evidence of thyroid tumors in male rats and liver tumors in male mice, the NOAEL used (1.12 mg/kg/day) for establishing the chronic reference dose (cRfD) is approximately 3-fold lower than the lowest dose that induced tumors (3.8 mg/kg/day). The Agency has determined that quantification of cancer risk using a non-linear approach (cRfD) would adequately account for all chronic toxicity, including carcinogenicity, which could result from exposure to fluazinam.

Specific information on the studies received and the nature of the adverse effects caused by fluazinam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in the document titled “Fluazinam. Human Health Risk Assessment to Support Section 3 Registration for New Uses on Tuberous and Corm, Subgroup 1C, Mayhaw, Squash/Cucumber Subgroup 9B; Amended Uses on Cabbage” on page 44 in docket ID number EPA-HQ-OPP-2015-0197.

#### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose

at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

A summary of the toxicological endpoints for fluazinam used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of November 7, 2012 (77 FR 66723) (FRL-9366-6).

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluazinam, EPA considered exposure under the petitioned-for tolerances as well as all existing fluazinam tolerances in 40 CFR 180.574. EPA assessed dietary exposures from fluazinam in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for fluazinam. In estimating acute dietary exposure, EPA used food consumption information from the 2003-2008 United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute analysis is based on tolerance-level residues for all commodities and uses



high-end residue estimates for the metabolite AMGT ((3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]amino]-2-nitro-6-(trifluoromethyl) phenyl]thio]-2-(beta-D-glucopyranosyloxy) propionic acid)). In addition, the acute assessment assumes 100 percent crop treated (PCT).

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, the chronic analysis is based on tolerance-level residues for all commodities except apples. For apples, the average field trial value was used. As with the acute assessment, it incorporates high-end estimates for AMGT, 100 PCT assumptions, default processing factors for all relevant processed commodities without a separate tolerance.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to fluazinam. Cancer risk was assessed using the same exposure estimates as discussed in Unit III.C.1.ii.

iv. *Anticipated residue and PCT information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluazinam and its

transformation products, including DCPA (6-(4-carboxy-3-chloro-2,6-dinitroanilino)-5-chloronicotinic acid), CAPA (3-chloro-6-(3-chloro-2,6-dinitro-4-trifluoromethyl anilino)nicotinic acid), DAPA (3-chloro-N<sup>4</sup>-(3-chloro-5-trifluoromethyl-2-pyridyl)- $\alpha,\alpha,\alpha$ -trifluorotoluene-3,5,5-triamine; 3-chloro-2(2,6-diamino-3-chloro- $\alpha,\alpha,\alpha$ -trifluoro-p-toluidino)-5-(trifluoromethyl)pyridine), HYPA (5-[[3-chloro-5-(trifluoromethyl-2-pyridyl)amino]- $\alpha,\alpha,\alpha$ -trifluoro-4,6-dinitro-o-cresol), and AMPA (2-(6-amino-3-chloro- $\alpha,\alpha,\alpha$ -trifluoro-2-nitro-p-toluidino)-3-chloro-5-(trifluoromethyl)pyridine).

These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluazinam and its transformation products. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide>.

Based on the First Index Reservoir Screening Tool (FIRST) and the Pesticide Root Zone Model Ground Water (PRZM GW) models, the estimated drinking water concentrations (EDWCs) for total residues of fluazinam and its transformation products for acute exposures are estimated to be 226 parts per billion (ppb) for surface water and 137 ppb for ground water and for chronic exposures are estimated to be 37.8 ppb for surface water and 119 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 226 ppb was used to assess the contribution to drinking water, and for the chronic dietary risk assessment, the water concentration of value 119 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Fluazinam is currently registered for the following uses that could result in residential exposures: golf course turf. EPA assessed residential exposure using the following assumptions: Only short-term dermal exposure is expected for residential post-application scenarios for children, teens, and adults who could potentially be exposed when they play golf on treated turf. No other residential exposures are expected. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

EPA has not found fluazinam to share a common mechanism of toxicity with any other substances, and fluazinam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluazinam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10x, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* There was no evidence of increased quantitative or qualitative susceptibility in the rabbit developmental or rat reproduction studies. However, quantitative susceptibility was seen in rat developmental and DNT studies where fetal/offspring effects were observed in the absence of maternal toxicity. The concern is low for the increased susceptibility noted in the studies since clear NOAELs are established, and the most sensitive endpoints/PODs are used for risk assessment and are protective of the observed susceptibility.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

- i. The toxicity database for fluazinam is complete.
- ii. Although indications of neurotoxicity and immunotoxicity were observed in the database for fluazinam, there were clear NOAELs for these effects, and the endpoints and doses for risk assessment are protective of the potential effects.
- iii. There is no evidence that fluazinam results in increased susceptibility in the rabbit developmental or rat reproduction studies. However, quantitative susceptibility was seen in rat

developmental and DNT studies where fetal/offspring effects were observed in the absence of maternal toxicity. The concern is low for the increased susceptibility noted in the studies since clear NOAELs are established, and the most sensitive endpoints/PODs are used for risk assessment.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues for all commodities except apples, where anticipated residues were used in the chronic assessment. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluazinam and its transformation products in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children. These assessments will not underestimate the exposure and risks posed by fluazinam.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluazinam will occupy 32% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazinam from food and water will utilize 92% of the cPAD for all infants, the population group receiving the greatest exposure. Based on

the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of fluazinam is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluazinam is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to fluazinam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 690 for children 6 to <11 years old, 820 for youth 11 to <16 years old and 890 for adults. Because EPA's level of concern for fluazinam is a MOE of 100 or below, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, fluazinam is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for fluazinam.

5. *Aggregate cancer risk for U.S. population.* EPA assessed cancer risk using a non-linear approach (i.e., RfD) since it adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to fluazinam. As the chronic dietary endpoint and dose are protective of potential cancer effects, fluazinam is not expected to pose an aggregate cancer risk.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to fluazinam residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

An adequate Gas Chromatography with Electron Capture Detector (GC/ECD) method is available for enforcing fluazinam tolerances on plant commodities.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL;

however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for fluazinam for any of the commodities covered by this action.

#### *C. Revisions to Petitioned-For Tolerances*

Because the tolerance level for the existing melon subgroup 9A is the same as the squash/cucumber subgroup 9B tolerance the Agency is establishing, the Agency is combining the tolerances for the two subgroups and establishing a tolerance for the entire cucurbit vegetable crop group 9.

### **V. Conclusion**

Therefore, tolerances are established for residues of fluazinam (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates in or on mayhaw at 2.0 ppm; cabbage at 3.0 ppm; cucurbit vegetables crop group 9 at 0.07 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. In addition, the existing tolerance on the vegetable, *Brassica* leafy, group 5 at 0.01 is modified to read “vegetable, *Brassica* leafy, group 5, except cabbage” at 0.01 ppm and the existing tolerance on potato at 0.02 ppm is removed as unnecessary since it is covered by the tolerance on the tuberous and corm subgroup 1C, and the melon subgroup 9A tolerance is removed since it is now replaced by the cucurbit vegetables crop group 9 tolerance.

### **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these



types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 31, 2016.

G. Jeffrey Herndon,  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.574, amend the table in paragraph (a)(1) as follows:

a. Alphabetically add the entries “Cabbage” and “Mayhaw”.

b. Remove the entries “Melon subgroup 9A” and “Potato”.

c. Remove the entry for “Vegetable, *Brassica* leafy, group 5” and alphabetically add entries for “Vegetable, *Brassica* leafy, group 5, except cabbage” and “Vegetable, tuberous and corm, subgroup 1C”.

The additions read as follows:

**§ 180.574 Fluazinam; tolerances for residues.**

(a) \* \* \* (1) \* \* \*

Commodity	Parts per million
* * *	* * * *
Cabbage	3.0
* * *	* * * *
Mayhaw	2.0
* * *	* * * *
Vegetable, <i>Brassica</i> leafy, group 5, except cabbage	0.01
Vegetable, cucurbit, group 9	0.07
* * *	* * * *
Vegetable, tuberous and corm, subgroup 1C	0.02

\* \* \* \*